

(K 964447)

April 16, 1997

**Summary of Safety and Effectiveness Information for
JJMI Polyurethane PICC and Midline Catheters**

1. Classification Name: Percutaneous Intravascular Catheter 80 FOZ
Common Name: Peripherally Inserted Central Venous Catheter (PICC)
and Midline catheter
Proprietary Name: None has been designated at this time
2. Establishment Registration Number: 2938241
3. Establishment Name/Address: Menlo Care, Inc.
Johnson & Johnson Medical, Inc.
1350 Willow Road Suite 202
Menlo Park, CA 94025
4. Classification: Class II
5. Substantially Equivalent Devices: L-Cath PICC and midline, One-Cath PICC and midline, Arrow PICC, SoloPICC and midline, Per-Q-Cath PICC, V-Cath PICC and midline, and SiL-Cath PICC and midline catheters.
6. Description and Device Function: Peripherally inserted central venous (PICC) and midline catheters placed for venous access or prolonged intravenous therapy. Method of insertion is through an introducer sheath. The optimal catheter tip location for the PICC catheter is in the superior vena cava of the heart. The recommended tip location for the midline catheter is below the shoulder, at the level of the axilla. The products will be available in single and dual lumen configurations; with and without a flushable guidewire; and as sterile individual units or in insertion kits containing the components used for insertion of the device.
7. Performance Standards: No performance standards have been established by the FDA for this type of device.

8. **Packaging and Sterilization:** These devices will be packaged in pouches and will be sterile and pyrogen-free. Insertion kits will be sterilized as well. Non-pyrogenicity will be established for each production lot by the LAL procedure.
9. **Tests/Studies with Conclusions:** The JJMI Polyurethane PICC and midline catheters have passed all tests for safety and effectiveness (*i.e.*, biocompatibility, sterility and device performance). The testing and conclusions are summarized below.

<u>Test</u>	<u>Conclusion</u>
Flow rate	Passed
Tensile strength of body	Passed
Tensile strength of catheter to hub	Passed
Catheter stiffness	Passed
Catheter elongation	Passed
Leakage at hub joint	Passed
Burst pressure (positive pressure)	Passed
Catheter collapse (negative pressure)	Passed
Biocompatibility per ISO 10993	Passed
Sterilization	Passed